

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Evaluation of the success rate of pulpal anesthesia in mandibular first molar following infiltration of 4% Articaine alone and as supplemental injection after inferior alveolar nerve block

Protocol summary

Summary

According to inclusion & exclusion criteria, volunteers will be selected and divided into 4 groups randomly. The clinician who does the injections will not be aware of study purpose. Also the person who does the electric pulp test (EPT); the volunteer and the statistical analyzer will not be aware of group codes. Intervention in each group will be as follow: Group 1- Inferior alveolar nerve block using 1 Lidocaine cartridge with epinephrine 1/80000. Group 2-Buccal infiltration of 1 Articaine cartridge with epinephrine 1/100000. Group 3-Buccal infiltration of 2 Articaine cartridge with epinephrine 1/100000. Group 4-Inferior alveolar nerve block using 1 Lidocaine cartridge with epinephrine 1/80000+buccal infiltration of 1 Articaine cartridge with epinephrine 1/100000. Before injection a control tooth (contralateral canine) will be tested to understand the accuracy of patient's response to EPT; for measuring the base line vitality, each tooth will be evaluated by EPT twice. After injection each tooth will be evaluated by EPT every 3 minutes; every minute the anesthesia of lip and tongue will be checked, up to 15 minutes. If the tooth will not response to 80 degree of EPT in 2 subsequence tests, it will be discerned "completely anesthetized". Finally the information will be recorded and in addition to the success rate the mean time for onset of anesthesia and its mean duration time will be evaluated.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201204109367N2**

Registration date: **2012-04-16, 1391/01/28**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2012-04-16, 1391/01/28

Registrant information

Name

Kaveh Oloumi

Name of organization / entity

Department of Endodontics, Faculty of Dentistry,
Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Zahedan University of Medical Sciences, Vce chancellor
for research

Expected recruitment start date

2012-04-20, 1391/02/01

Expected recruitment end date

2012-07-22, 1391/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the success rate of pulpal anesthesia in
mandibular first molar following infiltration of 4%
Articaine alone and as supplemental injection after
inferior alveolar nerve block

Public title

Evaluation of pulpal anesthesia with articaine

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients aged between 18-55 years old who have at least 1 vital first mandibular molar without any restoration or decay Exclusion criteria: 1.patients with systemic conditions which eliminate the use of epinephrine. 2.history of allergy to amide anesthetics or contents of local anesthetic cartridge. 3. pregnant women and 4. use of analgesics, opioids or any other drugs which influence the anesthesia.

Age

From **18 years** old to **55 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Zahedan University of Medical Sciences Ethics Committee

Street address

Vice Chancellor for Research - Pardis of Zahedan University of Medical Sciences – Khalij-e-Fars Blv. – Dr. Hesabi Sq.

City

Zahedan

Postal code

98167-43463

Approval date

2011-12-19, 1390/09/28

Ethics committee reference number

90-2347

Health conditions studied**1****Description of health condition studied**

Local Anesthesia

ICD-10 code

Y48.3

ICD-10 code description

Local anaesthetics

Primary outcomes**1****Description**

Success rate

Timepoint

Each 3 minutes after injection

Method of measurement

With electric pulp tester(EPT)

2**Description**

Onset of anesthesia

Timepoint

Each 3 minutes after injection

Method of measurement

With electric pulp tester(EPT)

3**Description**

Duration of anesthesia

Timepoint

Each 3 minutes after onset of anesthesia

Method of measurement

With electric pulp tester(EPT)

Secondary outcomes

empty

Intervention groups**1****Description**

Control: Inferior alveolar nerve block using 1 Lidocaine cartridge with epinephrine 1/80000

Category

Other

2**Description**

Intervention1: Buccal infiltration of 1 Articaine cartridge with epinephrine 1/100000

Category

Other

3

Description

Intervention 2: Buccal infiltration of 2 Articaine cartridge with epinephrine 1/100000

Category

Other

4

Description

Intervention 3: Inferior alveolar nerve block using 1 Lidocaine cartridge with epinephrine 1/80000+Buccal infiltration of 1 Articaine cartridge with epinephrine 1/100000

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Department of Endodontics, Faculty of Dentistry, Tehran University of Medical Sciences

Full name of responsible person

Dr. Kaveh Oloomi

Street address

Tehran Faculty of Dentistry, Northern Karegar St., Tehran.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences, Vice-chancellor for Research

Full name of responsible person

Mrs. Ashraf Zadeh

Street address

Pardis of Zahedan University of Medical Sciences, Khlij-e-Fars Blv., Dr. Hesabi Sq., Zahedan.

City

Zahedan

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Zahedan University of Medical Sciences, Vice-chancellor for Research

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Endodontics Department- Faculty of Dentistry- Tehran University of Medical Sciences

Full name of responsible person

Dr. Kaveh Oloomi

Position

Assistant Professor/Endodontist

Other areas of specialty/work

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty